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CALIFORNIA STEM CELL  
TREATMENT CENTER, INC.,  
CELL SURGICAL NETWORK  
CORPORATION, ELLIOT B. LANDER,  
and MARK BERMAN

**UNITED STATES DISTRICT COURT  
CENTRAL DISTRICT OF CALIFORNIA  
EASTERN DIVISION**

UNITED STATES OF AMERICA,

Plaintiff,

v.

CALIFORNIA STEM CELL  
TREATMENT CENTER, INC., a  
California corporation, CELL  
SURGICAL NETWORK  
CORPORATION, a California  
corporation, and ELLIOT B. LANDER,  
M.D., MARK BERMAN, M.D.,  
individuals,

Defendants.

CASE NO. 5:18-CV-01005-JGB-KK

Hon. Jesus G. Bernal  
Riverside, Courtroom 1

**DEFENDANTS' ANSWER TO  
COMPLAINT**

Action Filed: May 9, 2018  
Trial Date: None Set

Defendants California Stem Cell Treatment Center, Inc., Cell Surgical Network Corporation, Elliot B. Lander, and Mark Berman (“Defendants”), by and through their attorneys, hereby respond to the allegations in the numbered paragraphs of the Complaint filed by Plaintiff United States of America (“Plaintiff”) as follows:

1. This paragraph contains legal conclusions and does not require an answer. To the extent an answer is required, Defendants deny the allegations in this paragraph, and specifically deny that Defendants’ procedures are subject to regulation under the FDCA.

### **Jurisdiction and Venue**

2. This paragraph contains legal conclusions and does not require an answer. To the extent an answer is required, Defendants deny the allegations in this paragraph.

3. This paragraph contains legal conclusions and does not require an answer. To the extent an answer is required, Defendants deny the allegations in this paragraph.

### **Defendants and their Operations**

4. Admit.

5. Defendants admit that they conduct procedures involving extraction from a patient and reintroduction into the same patient of stromal vascular fraction using a patient’s own adipose tissue (“SVF procedure”), and further admit that they previously conducted procedures involving Vaccinia Vaccine, Live and SVF expanded in culture. Defendants otherwise deny the remaining allegations contained in the paragraph, including the characterization of the SVF as “manufactured,” and of the SVF procedure as a “product.”

6. This paragraph contains legal conclusions and does not require an answer. To the extent an answer is required, Defendants deny the characterization of the SVF procedure as a “product,” admit that the SVF procedure involves

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1 extraction from a patient and reintroduction into the same patient of stromal  
2 vascular fraction, and specifically deny that Defendants' procedures are subject to  
3 regulation under the FDCA.

4 7. Defendants deny the characterization of the SVF procedure as a  
5 "product," deny the characterization of the SVF procedure as an "experimental  
6 treatment," and further deny that the SVF procedure has been used to treat  
7 diabetes, but otherwise admit the allegations in this paragraph.

8 8. Defendants deny the characterization of the SVF procedure as a  
9 "product," and deny that SVF procedures involve injection into the brain or spinal  
10 cord, but otherwise admit the allegations in this paragraph.

11 9. Defendants deny that the SVF procedure "is the result of a multi-step  
12 manufacturing process," and further deny the characterization of the SVF  
13 procedure as a "product," but otherwise admit the remaining allegations contained  
14 in the paragraph.

15 10. Defendants deny that the SVF procedure involves "numerous  
16 processing steps," and deny the characterization of the SVF as "manufactured," but  
17 otherwise admit the remaining allegations contained in this paragraph.

18 11. Defendants deny the allegations contained in the first sentence of this  
19 paragraph, but otherwise admit the remaining allegations contained in this  
20 paragraph.

21 12. Defendants deny the characterization of the SVF procedure as a  
22 "product," and further deny the allegations contained in the first and second  
23 sentences of this paragraph. Defendants otherwise admit the remaining allegations  
24 contained in this paragraph. Defendants specifically deny that Defendants'  
25 procedures are subject to regulation under the FDCA.

26 13. Defendants deny the first sentence of this paragraph. Defendants  
27 further deny the characterization of the SVF procedure as a "product," deny the  
28 characterization of the SVF procedure as a "manufacturing process," and deny the

1 characterization of 0.9% Sodium Chloride Injection, USP and 5% Dextrose in  
2 Lactated Ringer's as "components." Defendants admit that the collagenase used in  
3 their procedures is received from Indiana. Defendants otherwise lack sufficient  
4 knowledge or information to form a belief as to the truth of remaining allegations  
5 in this paragraph and therefore deny them.

6 14. Defendants deny the characterization of the procedure as an  
7 "experimental treatment," as well as the characterization of the procedure as  
8 "manufacturing." Defendants otherwise admit the allegations contained in the  
9 second, third, and fifth sentences of this paragraph. Defendants further admit that  
10 they previously conducted procedures involving a combination of SVF and  
11 Vaccinia Vaccine, Live. The fourth sentence contains legal conclusions and does  
12 not require an answer. To the extent an answer is required, Defendants admit the  
13 allegations in the fourth sentence of this paragraph. Defendants otherwise deny the  
14 remaining allegations contained in this paragraph.

15 15. Defendants deny the characterization of the procedure as  
16 "manufactured," but otherwise admit the remaining allegations contained in this  
17 paragraph.

18 16. Defendants admit that they previously recovered adipose tissue and  
19 sent said tissue to a licensed facility as part of the expanded SVF procedure, and  
20 the resulting ATCELL was then returned to CSCTC Rancho Mirage and CSCTC  
21 Beverly Hills. Defendants otherwise deny the remaining allegations contained in  
22 this paragraph.

23 17. Defendants deny the characterization of the SVF procedure as a  
24 "product," and deny the characterization of the procedure as a "treatment," but  
25 otherwise admit the remaining allegations contained in this paragraph.

26 18. Defendants deny the characterization of the SVF procedure as a  
27 "product," and specifically deny that Defendants' procedures are subject to  
28

1 regulation under the FDCA, but otherwise admit the remaining allegations  
 2 contained in this paragraph.

3 19. Defendants deny the characterization of the SVF procedure as a  
 4 “product,” and specifically deny that Defendants’ procedures are subject to  
 5 regulation under the FDCA, but otherwise admit the remaining allegations  
 6 contained in this paragraph.

7 20. Defendants deny the characterization of the SVF procedure as a  
 8 “product,” and specifically deny that Defendants’ procedures are subject to  
 9 regulation under the FDCA, but otherwise admit the remaining allegations  
 10 contained in this paragraph.

11 21. Defendants admit the allegations contained in this paragraph.

12 22. Defendants deny the allegations contained in the first sentence of this  
 13 paragraph and deny the characterization of the SVF procedure as a “product,” but  
 14 otherwise admit the remaining allegations contained in this paragraph.

15 23. Defendants deny the first and second sentence of this paragraph, but  
 16 otherwise admit the remaining allegations contained in this paragraph.

17 24. Defendants lack sufficient knowledge or information to form a belief  
 18 as to the truth of the allegations in this paragraph and therefore deny them as  
 19 Plaintiff does not attach the Guidelines to which it refers.

20 25. Defendants admit the allegations contained in this paragraph.

21 26. Defendants deny the characterization that the SVF is “manufactured,”  
 22 and further deny the characterization of the SVF procedure as a “product,” but  
 23 otherwise admit the allegations contained in this paragraph.

24 27. Defendants deny the characterization of the SVF procedure as a  
 25 “product,” and further deny that the SVF is “manufactured,” but otherwise admit  
 26 the remaining allegations contained in this paragraph.

27 **The CSCTC Products Are Drugs Under the FDCA**

28 28. This paragraph contains legal conclusions and does not require an

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1 answer. To the extent an answer is required, Defendants deny the allegations in this  
2 paragraph. Defendants specifically deny that Defendants' procedures are subject to  
3 regulation under the FDCA.

4 29. This paragraph contains legal conclusions and does not require an  
5 answer. To the extent an answer is required, Defendants deny the allegations in this  
6 paragraph. Defendants specifically deny that Defendants' procedures are subject to  
7 regulation under the FDCA.

8 30. The first sentence of this paragraph contains legal conclusions and  
9 does not require an answer. To the extent an answer is required, Defendants deny  
10 the allegations contained in the first sentence of this paragraph. The allegations  
11 contained in the second sentence of this paragraph, including subparts (a) through  
12 (f) of this paragraph, purport to characterize the content of publicly-available  
13 sources, and Defendants specifically deny the characterization of those sources to  
14 the extent such characterizations are incomplete or inaccurate, and respectfully  
15 refer the Court to the full text of those sources. Defendants specifically deny that  
16 Defendants' procedures are subject to regulation under the FDCA.

17 31. This paragraph contains legal conclusions and does not require an  
18 answer. To the extent an answer is required, Defendants deny the allegations in this  
19 paragraph. Defendants specifically deny that Defendants' procedures are subject to  
20 regulation under the FDCA.

21 32. Defendants deny the allegations in this paragraph.

22 33. This paragraph contains legal conclusions and does not require an  
23 answer. To the extent an answer is required, Defendants deny the allegations in this  
24 paragraph. Defendants specifically deny that Defendants' procedures are subject to  
25 regulation under the FDCA.

26 **The CSCTC Products Are Biological Products Under the PHSA**

27 34. This paragraph contains legal conclusions and does not require an  
28 answer. To the extent an answer is required, Defendants deny the allegations in this

1 paragraph. Defendants specifically deny that Defendants' procedures are subject to  
2 regulation under the FDCA.

3 35. This paragraph contains legal conclusions and does not require an  
4 answer. To the extent an answer is required, Defendants deny the allegations in this  
5 paragraph. Defendants specifically deny that Defendants' procedures are subject to  
6 regulation under the FDCA.

7 36. This paragraph contains legal conclusions and does not require an  
8 answer. To the extent an answer is required, Defendants deny the allegations in this  
9 paragraph. Defendants specifically deny that Defendants' procedures are subject to  
10 regulation under the FDCA.

11 **The CSCTC Products Are Subject to Regulation Under the FDCA**

12 37. This paragraph contains legal conclusions and does not require an  
13 answer. To the extent an answer is required, Defendants deny the allegations in this  
14 paragraph. Defendants specifically deny that Defendants' procedures are subject to  
15 regulation under the FDCA.

16 38. This paragraph contains legal conclusions and does not require an  
17 answer. To the extent an answer is required, Defendants deny the allegations in this  
18 paragraph. Defendants specifically deny that Defendants' procedures are subject to  
19 regulation under the FDCA.

20 39. This paragraph contains legal conclusions and does not require an  
21 answer. To the extent an answer is required, Defendants deny the allegations in this  
22 paragraph. Defendants specifically deny that Defendants' procedures are subject to  
23 regulation under the FDCA.

24 40. This paragraph contains legal conclusions and does not require an  
25 answer. To the extent an answer is required, Defendants deny the allegations in this  
26 paragraph. Defendants specifically deny that Defendants' procedures are subject to  
27 regulation under the FDCA.  
28



1           41. Defendants reference and incorporate their Answer to paragraph 7 of  
2 Plaintiff's Complaint in response to the second sentence of this paragraph.  
3 Defendants further respond that the remaining allegations of this paragraph contain  
4 legal conclusions and do not require an answer. To the extent an answer is  
5 required, Defendants deny the allegations in this paragraph. Defendants  
6 specifically deny that Defendants' procedures are subject to regulation under the  
7 FDCA.

8           42. This paragraph contains legal conclusions and does not require an  
9 answer. To the extent an answer is required, Defendants deny the allegations in this  
10 paragraph. Defendants specifically deny that Defendants' procedures are subject to  
11 regulation under the FDCA.

12           43. This paragraph contains legal conclusions and does not require an  
13 answer. To the extent an answer is required, Defendants deny the allegations in this  
14 paragraph. Defendants specifically deny that Defendants' procedures are subject to  
15 regulation under the FDCA.

16           44. This paragraph contains legal conclusions and does not require an  
17 answer. To the extent an answer is required, Defendants deny the allegations in this  
18 paragraph. Defendants specifically deny that Defendants' procedures are subject to  
19 regulation under the FDCA.

20           45. This paragraph contains legal conclusions and does not require an  
21 answer. To the extent an answer is required, Defendants deny the allegations in this  
22 paragraph. Defendants specifically deny that Defendants' procedures are subject to  
23 regulation under the FDCA.

24           46. This paragraph contains legal conclusions and does not require an  
25 answer. To the extent an answer is required, Defendants deny the allegations in this  
26 paragraph. Defendants specifically deny that Defendants' procedures are subject to  
27 regulation under the FDCA.  
28



**The CSCTC Products Are Adulterated**

47. This paragraph contains legal conclusions and does not require an answer. To the extent an answer is required, Defendants deny the allegations in this paragraph. Defendants specifically deny that Defendants' procedures are subject to regulation under the FDCA.

48. Defendants admit the allegations contained in the first sentence of this paragraph. This remaining allegations of this paragraph contain legal conclusions and do not require an answer. To the extent an answer is required, Defendants deny the remaining allegations in this paragraph. Defendants specifically deny that Defendants' procedures are subject to regulation under the FDCA.

49. This paragraph contains legal conclusions and does not require an answer. To the extent an answer is required, Defendants deny the allegations in this paragraph. Defendants specifically deny that Defendants' procedures are subject to regulation under the FDCA.

**Adverse Events**

50. Defendants lack sufficient knowledge or information to form a belief as to what records the FDA investigators reviewed and otherwise deny the remaining allegations in this paragraph.

51. Defendants lack sufficient knowledge or information to form a belief as to what records the FDA investigators reviewed and otherwise deny the remaining allegations in this paragraph.

**The CSCTC Products Are Misbranded**

52. This paragraph contains legal conclusions and does not require an answer. To the extent an answer is required, Defendants deny the allegations in this paragraph. Defendants specifically deny that Defendants' procedures are subject to regulation under the FDCA.

53. This paragraph contains legal conclusions and does not require an answer. To the extent an answer is required, Defendants deny the allegations in this

1 paragraph. Defendants specifically deny that Defendants' procedures are subject to  
2 regulation under the FDCA.

3 54. This paragraph contains legal conclusions and does not require an  
4 answer. To the extent an answer is required, Defendants deny the allegations in this  
5 paragraph. Defendants specifically deny that Defendants' procedures are subject to  
6 regulation under the FDCA.

### 7 **Defendants Violate the FDCA**

8 55. Defendants deny the allegations in this paragraph. Defendants  
9 specifically deny that Defendants' procedures are subject to regulation under the  
10 FDCA.

11 56. Defendants deny the allegations in this paragraph. Defendants  
12 specifically deny that Defendants' procedures are subject to regulation under the  
13 FDCA.

14 57. Defendants deny the allegations in this paragraph. Defendants  
15 specifically deny that Defendants' procedures are subject to regulation under the  
16 FDCA.

### 17 **Continuing Noncompliance**

18 58. Defendants deny the allegations in this paragraph. Defendants  
19 specifically deny that Defendants' procedures are subject to regulation under the  
20 FDCA.

21 59. Defendants admit they were aware that an affiliate received a Warning  
22 Letter in December 2015, deny the characterization of the SVF as a "product," and  
23 otherwise lack sufficient knowledge or information to form a belief as to the truth  
24 of remaining allegations in this paragraph and therefore deny them. Defendants  
25 specifically deny that Defendants' procedures are subject to regulation under the  
26 FDCA.

27 60. Defendants admit that Defendants Lander and Berman participated in  
28 an interview with a professor at the University of California Davis School of

1 Medicine in February 2017. The remaining allegations in this paragraph purport to  
2 characterize the content of a publicly-available source, and Defendants specifically  
3 deny the characterization of that source to the extent such characterization is  
4 incomplete or inaccurate, and respectfully refer the Court to the full text of that  
5 source.

6 61. Defendants deny the characterization of the SVF procedure as a  
7 “product.” Defendants admit that in July 2017 FDA investigators conducted  
8 inspections at CSCTC Rancho Mirage and CSCTC Beverly Hills. Defendants  
9 further admit that during the time when FDA investigators were present at CSCTC  
10 Rancho Mirage and CSCTC Beverly Hills, Defendants Berman and Lander had  
11 discussions with FDA investigators, and during those discussions maintained that  
12 the SVF procedure is not a drug and is not subject to regulation under the FDCA.  
13 Defendants further admit that they sent written responses to the FDA regarding the  
14 inspections and responding to the reports. Those written submissions, among other  
15 things, demonstrate that Defendants’ practices are not subject to FDA oversight.  
16 Defendants deny any remaining allegations in this paragraph, and expressly deny  
17 that the FDA has jurisdiction over Defendants’ SVF procedure.

18 62. Defendants admit that Defendant Berman participated in a telephone  
19 call with FDA representatives in August 2017, and further admit generally that  
20 Defendant Berman stated that SVF is not a drug and is not subject to regulation  
21 under the FDCA. Defendants otherwise deny that the remaining allegations  
22 contained in the paragraph accurately or completely characterize the content of that  
23 conversation.

24 63. Defendants admit that in August 2017, United States Marshals seized  
25 five vials of ACAM2000 intended to be used by Defendants in an IRB-approved  
26 safety trial for end-stage cancer patients. Defendants lack sufficient knowledge or  
27 information to form a belief as to the truth of allegations contained in the second  
28 sentence of this paragraph and therefore deny them. The allegations contained in

the third sentence of this paragraph purport to characterize the content of a publicly-available source, and Defendants specifically deny the characterization of that source to the extent such characterization is incomplete or inaccurate, and respectfully refer the Court to the full text of the source. Defendants otherwise deny the remaining allegations contained in this paragraph.

64. Defendants deny the characterization of the SVF procedure as a “product,” but admit that Defendants Lander and Berman communicated with the FDA in October 2017. Defendants admit the second sentence of this paragraph. Defendants specifically deny that Defendants’ procedures are subject to regulation under the FDCA.

65. Defendants deny the allegations in this paragraph.

#### PLAINTIFF’S PRAYER FOR RELIEF

I. Defendants deny Plaintiff is entitled to such relief.

II. Defendants deny Plaintiff is entitled to such relief.

III. Defendants deny Plaintiff is entitled to such relief.

#### **AFFIRMATIVE DEFENSES**

Further responding to the Complaint and as additional defenses thereto, Defendants assert the following affirmative defenses, without admitting any allegations of the Complaint not previously admitted, and without admitting that the Defendants bear the burden of proof or burden of persuasion on any matter set forth herein.

#### **FIRST AFFIRMATIVE DEFENSE**

This Court lacks subject matter jurisdiction to hear this action.

#### **SECOND AFFIRMATIVE DEFENSE**

The Complaint fails to state a claim upon which relief can be granted.

#### **THIRD AFFIRMATIVE DEFENSE**

Plaintiff’s claim fails because the SVF procedures fall within the “same surgical procedure exception.”

**FOURTH AFFIRMATIVE DEFENSE**

The relief sought in the Complaint is barred by the due process clause of the United States Constitution.

**FIFTH AFFIRMATIVE DEFENSE**

The relief sought in the Complaint is barred as a violation of the Administrative Procedure Act.

**SIXTH AFFIRMATIVE DEFENSE**

The relief sought in the Complaint is barred under the Tenth Amendment to the United States Constitution.

**SEVENTH AFFIRMATIVE DEFENSE**

The relief sought in the Complaint violates patients' right to privacy guaranteed by the United States Constitution.

**EIGHTH AFFIRMATIVE DEFENSE**

The relief sought in the Complaint is barred by the doctrines of laches and estoppel.

**RESERVATION OF DEFENSES**

Defendants reserve the right to assert additional affirmative defenses in the event that clarification of Plaintiff's allegations and/or discovery reveals any such defenses to be appropriate.

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**REQUEST FOR RELIEF**

WHEREFORE, Defendants respectfully request that the Court render a judgment as follows:

- (a) That Plaintiff be denied all forms of relief requested in the Complaint;
- (b) That the Complaint be dismissed with prejudice and judgment entered in favor of Defendants;
- (c) That Defendants be awarded their costs and attorneys' fees to the extent allowable by law; and
- (d) For such other and further relief as the Court deems just and proper.

Dated: July 17, 2018

**VENABLE LLP**

By: /s/ Witt W. Chang  
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